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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,441

08/20/2003

Nicholas J.P. Ryba

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7590

05/05/2006

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,441

Applicant(s)

RYBA ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 55-88 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 55-60, 64, 65, 71-74 drawn to T1R3 polypeptides, classified in class 530, subclass 350.
- II. Claims 61-63, 66, drawn to T1R3/T1R2 heteromeric polypeptides, classified in class 530, subclass 402.
- III. Claims 67, 69, 70, 75, as the claim relates to T1R3, drawn to T1R3 binding antibodies, classified in class 530, subclass 388.22.
- IV. Claims 66, 68 as the claims relate to T1R3/T1R1 heteromeric receptor, drawn to T1R3/T1R1 binding antibodies, classified in class 530, subclass 388.22.
- V. Claim 84, as the claim relates to T1R2, drawn to T1R2 binding antibodies, classified in class 530, subclass 388.22.
- VI. Claims 76-79 drawn to T1R3 polynucleotides, classified in class 536, subclass 23.5.
- VII. Claims 80-83 drawn to T1R2 polypeptides, classified in class 530, subclass 350.
- VIII. Claims 85-88 drawn to T1R2 polynucleotides, classified in class 536, subclass 23.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and VII are related to the invention of Group II as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product

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(MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)).

In the instant case, the intermediate product of Group I is deemed to be useful to produce antibodies specific to a T1R3 receptor and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Similarly, the intermediate product of Group VII is deemed to be useful to produce antibodies specific to a T1R2 receptor. Further, the skilled artisan would expect that the intermediate product of Group I or VII would lose its particular functional identity, e.g. specific signaling properties, as part of the heterodimeric receptor of Group II (MPEP § 806.04(b)). Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Although there are no provisions under the section for “Relationship of Inventions” in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: The protein and protein complexes of Groups I, II, and VII, the antibodies of Groups III-V and the polynucleotides of Groups VI and VIII are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. The proteins of Groups I, II, and VII can be used in materially different methods other than to make the antibodies of Groups III-V, such as in assays of taste. The antibodies of Groups III-V can be obtained through expression of the DNA

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encoding the protein of Groups I, II, and VII and can be used ways other than to isolate the protein of Groups I, II, and VII, such as in immunohistochemical and diagnostic uses.

Additionally, the antibodies of Groups III-V independent and patentably distinct from each other because one is not required for the use of the other. Further, the protein of Groups I, II and VII can be prepared by processes which are materially different from recombinant DNA expression of Groups VI and VIII, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Groups VI and VIII can be used other than to make the protein of Groups I, II and VII, such in gene therapy or as a probe in nucleic acid hybridization assays. The polynucleotides of Groups VI and VIII independent and patentably distinct from each other because one is not required for the use of the other. Finally, although the antibodies of Groups III-V can be used to obtain the DNA of Groups VI and VIII, they can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

Claims 55-83 are generic to a plurality of disclosed patentably distinct species of inventions, each relating to a particular T1R3 polypeptide (SEQ ID NO: 15, 20, 23, 25) or T1R3 polynucleotide (SEQ ID NO: 14, 19, 22, 24), or a particular T1R2 polypeptide (SEQ ID NO 7, 8, or 9), or a particular T1R2 polynucleotide of SEQ ID NO: 10, 11 or 12, or particular antibodies specific to either SEQ ID NO: 7, 8, 9, 15, 20, 23, 25 or specific to a complex between a

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particular T1R2/T1R3. Each invention is patentably distinct, the use of one not being required for the use of any other. Each SEQ ID NO, or antibody specific to it, represents a structurally and functionally distinct molecule, and although a search of one SEQ ID NO may overlap that of another, no two searches would be coextensive, and nor could one search be relied upon to provide art that is anticipatory or might render obvious any other SEQ ID NO. To search all species of invention in a single application would be unduly burdensome.

Thus, if either of Group I , II, V-VIII is elected, then Applicant is required under 35 U.S.C. 121 to additionally elect a single disclosed species, such species consisting of single SEQ ID NO designating a particular polynucleotide, polypeptide or antibody specific to it.

If either of Group II or IV is elected, then Applicant is required under 35 U.S.C. 121 to additionally elect a single disclosed species of T1R2 and a single T1R3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



April 26, 2006



**ELIZABETH KEMMERER
PRIMARY EXAMINER**